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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/661,402	09/12/2003	Andrew Vaillant	16051-7US CC	6670

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EXAMINER	
HURT, SHARON L	
ART UNIT	**PAPER NUMBER**
1648	

DATE MAILED: 11/04/2005

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	10/661,402	VAILLANT ET AL.	
	Examiner	Art Unit	
	Sharon Hurt	1648	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 1 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☐ Responsive to communication(s) filed on _____.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) 1-57 is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☐ Claim(s) _____ is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) 1-57 are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____.
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: _____.

DETAILED ACTION

Election/Restrictions

Restriction to one of the following inventions is required under 35 U.S.C. 121:

I. Claims 52-56, are drawn to a method for selecting an antiviral oligonucleotide for use against a target virus, classified in class 435, subclass 5.

II. Claim 57, is drawn to a method for the treatment of a viral infection by administering a therapeutically effective amount of at least one pharmacologically acceptable oligonucleotide randomer at least 10 nucleotides in length, classified in class 514, subclass 44.

III. Claims 1-21, and 33-51 are drawn to a method of treatment of a viral infection by administering a therapeutically effective amount of at least one pharmacologically acceptable oligonucleotide at least 10 nucleotides in length, classified in class 514, subclass 44. If this group is elected, election of species is further required.

IV. Claims 22-51 are drawn to an antiviral pharmaceutical composition, classified in class 514, subclass 44. If this group is elected, election of species is further required.

The inventions are distinct, each from the other because:

Group I is drawn to a method for selecting an antiviral oligonucleotide. Group II is drawn to a method for treatment of a viral infection with an oligonucleotide randomer, a population of oligonucleotides by definition. Group III is drawn to a method of treatment of a viral infection with an oligonucleotide. Group IV is drawn to an antiviral composition.

Group I is unrelated to Groups II – IV, although the screening of Group I could be used to identify the oligonucleotides of Group III and IV. An identical oligonucleotide could be identified by a materially different method such as a method of binding to a viral component. Groups II and III are distinct because Group III requires one oligonucleotide (or more), but Group II requires a randomer, which by definition is a large population of oligonucleotides.

Inventions of Group II and Group III are related as combination and subcombination. Inventions in this relationship are distinct if it can be shown that (1) the combination as claimed does not require the particulars of the subcombination as claimed for patentability, and (2) that the subcombination has utility by itself or in other combinations (MPEP § 806.05(c)). In the instant case, the combination as claimed does not require the particulars of the subcombination as claimed because a randomer includes many oligonucleotides and the oligonucleotide can be single. The subcombination has separate utility such as treating a virus infection without any other oligonucleotides.

Inventions in Group III and Group IV are related as product and process of use. The inventions can be shown to be distinct if either or both of the following can be

shown: (1) the process for using the product as claimed can be practiced with another materially different product or (2) the product as claimed can be used in a materially different process of using that product (MPEP § 806.05(h)). In the instant case the antiviral composition could be used in a different method such as decontamination of biological products.

Because these inventions are distinct for the reasons given above and the search required for Groups is different and have acquired a separate status in the art as shown by their different classification, restriction for examination purposes as indicated is proper.

Group III contains claims directed to the following patentably distinct species of the claimed invention in claims 3-21, virus families:

1. Retroviridae
2. Herpesviridae
3. Hepadnaviridae
4. Paramyxoviridae
5. Parvoviridae
6. Poxviridae
7. Papillomaviridae
8. Adenoviridae
9. Bunyaviridae
10. Picornaviridae
11. Flaviviridae
12. Filoviridae
13. Orthomyxoviridae
14. Togaviridae
15. Coronaviridae

16. Reoviridae
17. Rhabdoviridae
18. Arenaviridae
19. Calciviridae

Applicant is required under 35 U.S.C. 121 to elect a single disclosed species for prosecution on the merits to which the claims shall be restricted if no generic claim is finally held to be allowable. Currently claims 1-2 and 33-51 are generic.

Groups III also claims "at least one" oligonucleotide "at least 10 nucleotides in length". Group IV also claims "at least one" oligonucleotide "at least 10 nucleotides in length". Applicant is required to elect an oligonucleotide of specified length.

In Groups III and IV, Claims 1-51 are generic to a plurality of disclosed patentably distinct species comprising all oligonucleotides of at least 10 bases in length. Applicant is required under 35 U.S.C. 121 to elect a single disclosed species, even though this requirement may be traversed.

Applicant is required under 35 U.S.C. 121 to elect a single disclosed species for prosecution on the merits to which the claims shall be restricted if no generic claim is finally held to be allowable. Currently in Group III, claims 1-21 and 33-51 are generic and in Group IV, claims 22-51 are generic.

Burden consists not only of specific searching of classes and subclasses, but also of searching multiple databases for foreign references and literature searches. Burden also resides in the examination of independent claim sets for clarity, enablement and double patenting issues. Burden for oligonucleotides requires search of an

astronomical number of different oligonucleotides and also determination of whether or not a pre-existing oligonucleotide meets the functional limitation recited in the claims. Burden for treatment of different viruses involves a search for each virus family and determining enablement of claimed pharmacological use. Each virus has a different sequence therefore requires a separate search to exclude sequence complementary.

Applicant is advised that a reply to this requirement must include an identification of the species that is elected consonant with this requirement, and a listing of all claims readable thereon, including any claims subsequently added. An argument that a claim is allowable or that all claims are generic is considered nonresponsive unless accompanied by an election.

Upon the allowance of a generic claim, applicant will be entitled to consideration of claims to additional species which are written in dependent form or otherwise include all the limitations of an allowed generic claim as provided by 37 CFR 1.141. If claims are added after the election, applicant must indicate which are readable upon the elected species. MPEP § 809.02(a).

Should applicant traverse on the ground that the species are not patentably distinct, applicant should submit evidence or identify such evidence now of record showing the species to be obvious variants or clearly admit on the record that this is the case. In either instance, if the examiner finds one of the inventions unpatentable over the prior art, the evidence or admission may be used in a rejection under 35 U.S.C. 103(a) of the other invention.

Applicant is reminded that upon the cancellation of claims to a non-elected invention, the inventorship must be amended in compliance with 37 CFR 1.48(b) if one or more of the currently named inventors is no longer an inventor of at least one claim remaining in the application. Any amendment of inventorship must be accompanied by a request under 37 CFR 1.48(b) and by the fee required under 37 CFR 1.17(i).

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Sharon Hurt whose telephone number is 571-272-3334. The examiner can normally be reached on M-F 8:00 - 4:00 PM.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Housel James can be reached on 571-272-0902. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

MARY E. MOSHER, PH.D.
PRIMARY EXAMINER

November 1, 2005